

AcceleDent as a Means for Pain Reduction

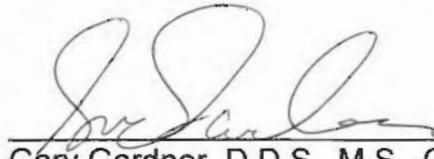
During Orthodontic Treatment

Wendy D. Lobre

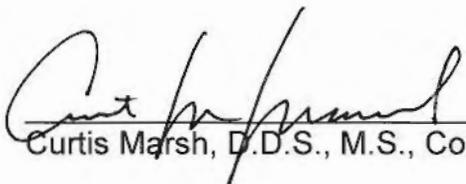
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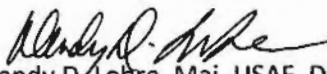
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AcceleDent as a Means for Pain Reduction

During Orthodontic Treatment

A THESIS

Presented to the Faculty of

Uniform Services University of the Health Sciences

In Partial Fulfillment

of the Requirements

for the Degree of

MASTER OF SCIENCE

By

Wendy D. Lobre, BS, DDS

San Antonio, TX

May 30, 2015

The views expressed in this study are those of the authors and do not reflect the official policy of the United States Air Force, the Department of Defense, or the United States Government. The authors do not have any financial interest in the companies whose materials are discussed in this article.

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DEDICATION

This thesis is dedicated to my family. Without their support, I could not have made it this far. Thank you to my loving husband, Paul, for being a constant source of support and encouragement during the challenges residency. I am truly honored to have you in my life. Thank you to Madison, Kyros, Kayler and Carter for reminding me to take time to play and focus on what's truly important in life.

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ABSTRACT

Purpose: The purpose of this study was to investigate the AcceleDent Aura vibration therapy as a means of pain reduction compared to a no therapy control group during comprehensive orthodontic treatment. **Methods:** The study group consisted of 58 patients selected from those who presented for treatment at the Air Force Post Graduate Dental School Department of Orthodontics. Patients were randomly assigned to the control group or the AcceleDent group. Patients in both groups were given routine post treatment instructions and were asked to complete a Visual Analog Scale questionnaire at appropriate intervals during the weeks after the separator or archwire appointment. **Results:** Patients using the AcceleDent Aura device reported lower average pain levels. Statistical differences were determined at the $p \leq 0.05$ level of significance. **Conclusion:** There is a statistically significant difference over time in overall pain and biting pain in patients using the AcceleDent Aura device as compared to patients not using the device.

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I. INTRODUCTION

Pain is a common side effect of orthodontic treatment and a major deterrent for many patients. It is a complex phenomenon involving multiple variants. Pain is influenced by factors such as age, gender, individual pain threshold, how much force is applied and prior experiences of pain (Scheurer et al., 1996). In orthodontic treatment a mechanical stimulus is introduced by placing fixed or removable appliances on the teeth resulting in tooth movement. In order to achieve this movement, forces are applied to the dentoalveolar complex resulting in inflammation or ischemia to the periodontal ligament (PDL) with subsequent release of histamine, bradykinin, prostaglandins, serotonin and substance P (Skjelbred and Lökken, 1997). These mediators stimulate local nerve endings and send pain signals to the brain.

Many methods have been utilized to alleviate pain arising from orthodontic origins. Until recently, non-steroidal anti-inflammatory drugs (NSAIDS) were the most common method employed for pain relief. Simply, NSAIDS block the formation of arachidonic acid in the production cycle of prostaglandin, thus prostaglandin levels are reduced and pain is diminished (Ngan et al., 1994). Other alternatives include low-level laser therapy (Lim et al., 1995), transcutaneous electrical nerve stimulation (TENS) (Roth and Thrash, 1986), vibratory stimulation of the PDL (Ste Marie et al., 2003), viscoelastic bite wafers (Farzanegan et al., 2012) or even chewing gum (Proffit and Fields, 2000).

The mechanism of these methods is to relieve compression of the PDL, restoring normal vascular and lymphatic circulation, which helps eliminate edema and inflammation and thus reduces pain and discomfort (Furstman and Bernik,

1972). These methods also have direct influence on mechanoreceptors. There are four principal types of mechanoreceptors in the orofacial complex. The Meissner corpuscles respond to light touch and adapt rapidly to changes in frequency, velocity and direction (vibrations around 50 Hz). These are found mainly in the mid-root area of teeth. The Ruffini corpuscles detect tension deep in the skin and fascia, and are primarily located in the apical area of teeth. The Merkel nerve endings detect sustained pressure in the mucosa. The Pacinian corpuscles in the skin and fascia detect rapid vibrations (of about 100–300 Hz) (Tsuchitani, 1997). Each of these receptors process information to ensure proper functioning of the orofacial complex.

The primary focus of this study was vibration therapy as a means of pain reduction. Previous studies have demonstrated that vibration effectively reduces pain originating from teeth or the surrounding tissues (Ottoson et al., 1981). As previously discussed, vibration may help relieve compression of the periodontal ligament (PDL), promoting normal circulation which prevents build-up of inflammatory by-products, thus reducing pain. Another possibility is the "gate control" theory, which suggests pain can be reduced by simultaneous activation of nerve fibers that conduct non-noxious stimuli (Melzack and Wall, 1965). Similar to pain relieving effects from TENS, the effect of vibration seems consistent with the "gate control" theory, relying on activation of rapidly adapting mechanoreceptors in the skin, periosteum, muscle and bone, and an interaction between large fibers and small pain fibers. In essence, the receptors activated by vibration could mask the pain signals and prevent them from reaching the central nervous system (CNS).

AcceleDent is patented as a “Vibrating Orthodontic Remodeling Device” (U.S. Department of Commerce’s United States Patent and Trademark Office, 2013). It made its international debut in 2009 and has been available on the US market since 2012. It is a Food and Drug Administration (FDA) approved, Class II medical device designed for faster orthodontic treatment. This device applies cyclic forces to the dentition and its “safe acceleration of the bone remodeling process complements conventional orthodontic treatment”. The application of these cyclical forces induces accelerated remodeling of alveolar bone, thereby enabling accelerated tooth movement. In a series of rabbit experiments, Mao demonstrated that cyclical forces applied at 2 N and with frequencies of 0.2 and 1 Hz for 20 minutes daily provided in conjunction with typical static orthodontic forces provided 24-hours per day induced increased cranial growth, sutural separation, and proliferation of osteoblast-like cells (Mao and Nah, 2004). The primary purpose for using AcceleDent is to decrease overall orthodontic treatment time. Additionally, this type of device idea (cyclic force) has been used and approved for use in other areas of the body (e.g., the Juvent 1000 device for maintaining and/or enhancing muscle strength, function, and postural stability).

II. OBJECTIVES

A. Purpose of Study

Many clinicians have noted pain reduction as an additional benefit for those patients utilizing AcceleDent. The purpose of this study is to compare the pain levels during the first four months of orthodontic treatment in patients using AcceleDent Aura versus patients utilizing no pain control methods.

B. Specific Hypothesis

There will be a decrease in pain levels for patients using AcceleDent Aura as compared to those patients that did not use the device.

C. Null Hypothesis

There will be no difference in pain levels for patients using AcceleDent Aura as compared to those patients that did not use the device.

III. MATERIALS AND METHODS

A. Experimental Design

Sixty-four patients beginning treatment at the Air Force Postgraduate Dental School, Department of Orthodontics Clinic and meeting the following inclusion criteria were enrolled in the study: (1) comprehensive orthodontic treatment (2) not using any investigational drug or other investigational device (3) no pre-existing pain conditions and (4) willing to forgo the use of aspirin or other non-steroidal anti-inflammatory drugs during the course of the study. Fifty eight of the 64 patients completed the study. The study population consisted of 37 male and 27 female adult and adolescent patients, treated by the staff and residents at the Tri-Service Orthodontic Residency Program.

Approval from the Wilford Hall Ambulatory Surgical Center Institutional Review Board (WHASCIRB) was obtained prior to patient recruitment (Protocol # FWH20140049H/IRBNet #397104-2). At the time of recruitment, all patients meeting the inclusion criteria, and their parents if necessary, were given an explanation of the study by the principal investigator and consented to participation in the study by signing consent forms.

The subjects were assigned to the experimental (AcceleDent) or control group by block randomization. To simplify tracking and blind the data sets, the following system was used: the AcceleDent Aura serial number was assigned as the participant number, and a CG#1-33 was assigned to each control group subject. The AcceleDent group consisted of 31 patients (14 female, 17 male)

with a mean age of 23 years. The control group consisted of 33 patients (13 female, 20 male) with a mean age of 21.5 years.

All subjects were given routine post treatment instructions and asked to complete a questionnaire at appropriate intervals during the days/weeks after the separator or arch wire appointment. The questionnaire was in the format of a multi-page booklet that contained a series of 10-cm horizontal visual analog scales (VAS) (Fig 3-4) on which the patient marked the degree of discomfort (none to worst pain possible) at the indicated time periods. The patients were instructed to make a mark on the scale at each time interval to represent the perceived severity of pain for the following categories: chewing/biting pain and overall pain. The incidence and severity of pain were recorded by the patient after separator or arch wire placement daily for the first seven days and then weekly for the remainder of the month. This protocol was repeated for the first four months of orthodontic treatment.

Patients were encouraged not to take any analgesics. If “rescue” medication was needed, they were instructed to indicate on the questionnaire the date, time, dosage, and specific “rescue” medication taken. These patients were not excluded from the study, but the implications were included in the discussion.

B. The Study Device

The device used in this study was the AcceleDent Aura by OrthoAccel Technologies Inc, Houston, TX (Fig 3-1). The device was used per manufacturer guidelines throughout the study. The primary components of the device are the

activator and the mouthpiece. The activator is battery powered and delivers gentle micropulses (0.25 N at 30 Hz) created by two weights being rotated by the motor. It includes a USB interface for recharging and downloading usage history. The mouthpiece provides a comfortable fit and snaps easily on and off the activator for transport and cleaning (Fig 3-2). The patient bites on the mouthpiece after activating the device, and the vibration is transferred to the teeth (Fig 3-3). Patients assigned to the experimental group were instructed to use the AcceleDent Aura device for 20 minutes daily beginning the day separators or arch wires were placed. At the completion of the four month study, patients were allowed to continue using the AcceleDent Aura if desired.

C. Survey for Pain Measurement

The VAS was selected as the measurement tool for this study, as it has been validated and used extensively in randomized trials (Conti, 2006) and has shown good construct validity in comparison with other pain measures (Breivik, 2000). The pain VAS is a continuous scale comprised of a horizontal line, usually 10 centimeters (100 mm) in length, anchored by two verbal descriptors, one for each symptom extreme. For pain intensity, the scale is most commonly anchored by “no pain” (score of 0) and “worst possible pain” (score of 100). Pain surveys were completed daily for the first seven days after appliance or arch wire placement, and then weekly for the next three weeks.

D. Figures of Materials and Methods Procedures

The images of the research procedures are listed and documented in the order of their occurrence.

Figure 3-1. AcceleDent Aura Device



Figure 3-2. Patient Kit



Figure 3-3. AcceleDent Aura in use

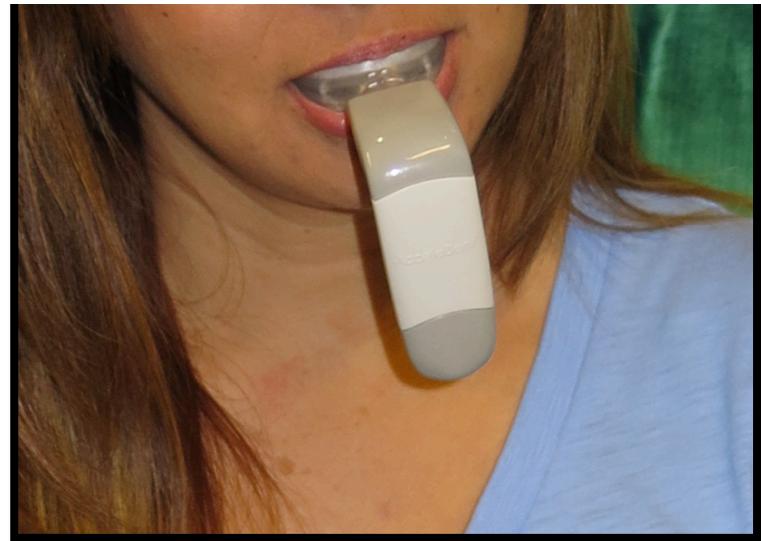


Figure 3-4. Visual Analog Scale



IV. RESULTS

There were a total of 40 data points for each subject in the study. The results for mean pain scores are reported in Tables 4-1 to 4-9 and graphed across time by day, week and month (Figures 4-3 to 4-11). Mean pain scores were numerically generated from patients' VAS information (0-100). P values are compared to the control groups. Pain scores from the first seven days were averaged to make the first week score. After the first week, pain was scored once weekly for the following three weeks. The four weekly pain scores were averaged again to represent a monthly score. Mann Whitney-U tests were used to detect differences between the control groups and the AcceleDent groups ($\alpha=0.05$). The AcceleDent group was more effective at controlling pain than the group that didn't use the device. The perceived pain was lower in the AcceleDent group, with significantly lower scores in all categories of overall pain and in the last two months for biting pain (Table 4-1). On average, perceived pain peaked by the second day. Pain levels decreased over time in both groups (Figure 4-3), regardless of treatment modality. The results for each time interval and the overall study were compiled and the results are summarized below:

Table 4-1. Overall Study Results and Monthly Comparisons

| Month | AcceleDent Overall Pain | AcceleDent Biting Pain | Control Overall Pain | Control Biting Pain |
|----------------------|------------------------------------|-----------------------------------|---------------------------------|--------------------------------|
| Month 1 | 11.6 (p=0.049) | 18.3 (p=0.070) | 20.0 | 35.5 |
| Month 2 | 5.9 (p=0.002) | 8.2 (p=0.054) | 11.9 | 18.7 |
| Month 3 | 3.4 (p=0.037) | 4.7 (p=0.045) | 11.7 | 15.9 |
| Month 4 | 1.4 (p=0.001) | 2.4 (p=0.004) | 12.2 | 20.2 |
| Overall Study | 9.3 (p=0.004) | 14.7 (p=0.046) | 20.3 | 27.0 |

Table 4-2. Month 1 Weekly Comparisons

| Month 1 | AcceleDent Overall Pain | AcceleDent Biting Pain | Control Overall Pain | Control Biting Pain |
|----------------|------------------------------------|-----------------------------------|---------------------------------|--------------------------------|
| Week 1 | 20.2 | 29.2 | 27.6 | 36.8 |
| Week 2 | 6.1 | 11.1 | 16.7 | 23.2 |
| Week 3 | 4.6 | 8.2 | 9.6 | 14.5 |
| Week 4 | 3.4 | 7.2 | 8.0 | 11.2 |

Table 4-3. Month 2 Weekly Comparisons

| Month 2 | AcceleDent Overall Pain | AcceleDent Biting Pain | Control Overall Pain | Control Biting Pain |
|----------------|------------------------------------|-----------------------------------|---------------------------------|--------------------------------|
| Week 1 | 12.6 | 22.6 | 26.6 | 34.4 |
| Week 2 | 3.0 | 5.0 | 14.1 | 18.1 |
| Week 3 | 2.0 | 4.0 | 7.8 | 9.8 |
| Week 4 | 1.2 | 2.4 | 3.9 | 5.7 |

Table 4-4. Month 3 Weekly Comparisons

| Month 3 | AcceleDent Overall Pain | AcceleDent Biting Pain | Control Overall Pain | Control Biting Pain |
|----------------|------------------------------------|-----------------------------------|---------------------------------|--------------------------------|
| Week 1 | 9.5 | 15.5 | 21.9 | 29.1 |
| Week 2 | 2.2 | 3.5 | 6.4 | 8.1 |
| Week 3 | 1.7 | 2.3 | 5.2 | 7.2 |
| Week 4 | 1.5 | 2.4 | 3.1 | 4.5 |

Table 4-5. Month 4 Weekly Comparisons

| Month 4 | AcceleDent Overall Pain | AcceleDent Biting Pain | Control Overall Pain | Control Biting Pain |
|----------------|------------------------------------|-----------------------------------|---------------------------------|--------------------------------|
| Week 1 | 5.1 | 9.1 | 19.6 | 26.0 |
| Week 2 | 1.3 | 2.7 | 6.7 | 12.0 |
| Week 3 | 0.8 | 1.1 | 4.7 | 7.5 |
| Week 4 | 1.9 | 2.9 | 3.3 | 5.8 |

Table 4-6. Month 1 Daily Comparisons

| Month 1 | AcceleDent Overall Pain | AcceleDent Biting Pain | Control Overall Pain | Control Biting Pain |
|----------------|------------------------------------|-----------------------------------|---------------------------------|--------------------------------|
| Day 1 | 29.8 | 43.3 | 43.8 | 57.9 |
| Day 2 | 36.8 | 47.8 | 48.9 | 62.2 |
| Day 3 | 24.5 | 35.4 | 46.3 | 59.7 |
| Day 4 | 18.6 | 27.4 | 38.2 | 49.3 |
| Day 5 | 12.9 | 21.5 | 28.9 | 36.6 |
| Day 6 | 11.3 | 16.4 | 20.3 | 28.9 |
| Day 7 | 7.3 | 13.0 | 15.2 | 24.8 |

Table 4-7. Month 2 Daily Comparisons

| Month 2 | AcceleDent Overall Pain | AcceleDent Biting Pain | Control Overall Pain | Control Biting Pain |
|----------------|------------------------------------|-----------------------------------|---------------------------------|--------------------------------|
| Day 1 | 22.4 | 31.1 | 31.8 | 29.2 |
| Day 2 | 20.3 | 32.7 | 33.9 | 43.8 |
| Day 3 | 13.7 | 26.2 | 33.5 | 41.4 |
| Day 4 | 11.2 | 22.1 | 30.1 | 38.0 |
| Day 5 | 7.0 | 16.3 | 22.9 | 29.5 |
| Day 6 | 6.0 | 14.4 | 19.0 | 26.8 |
| Day 7 | 5.4 | 10.7 | 15.3 | 22.5 |

Table 4-8. Month 3 Daily Comparisons

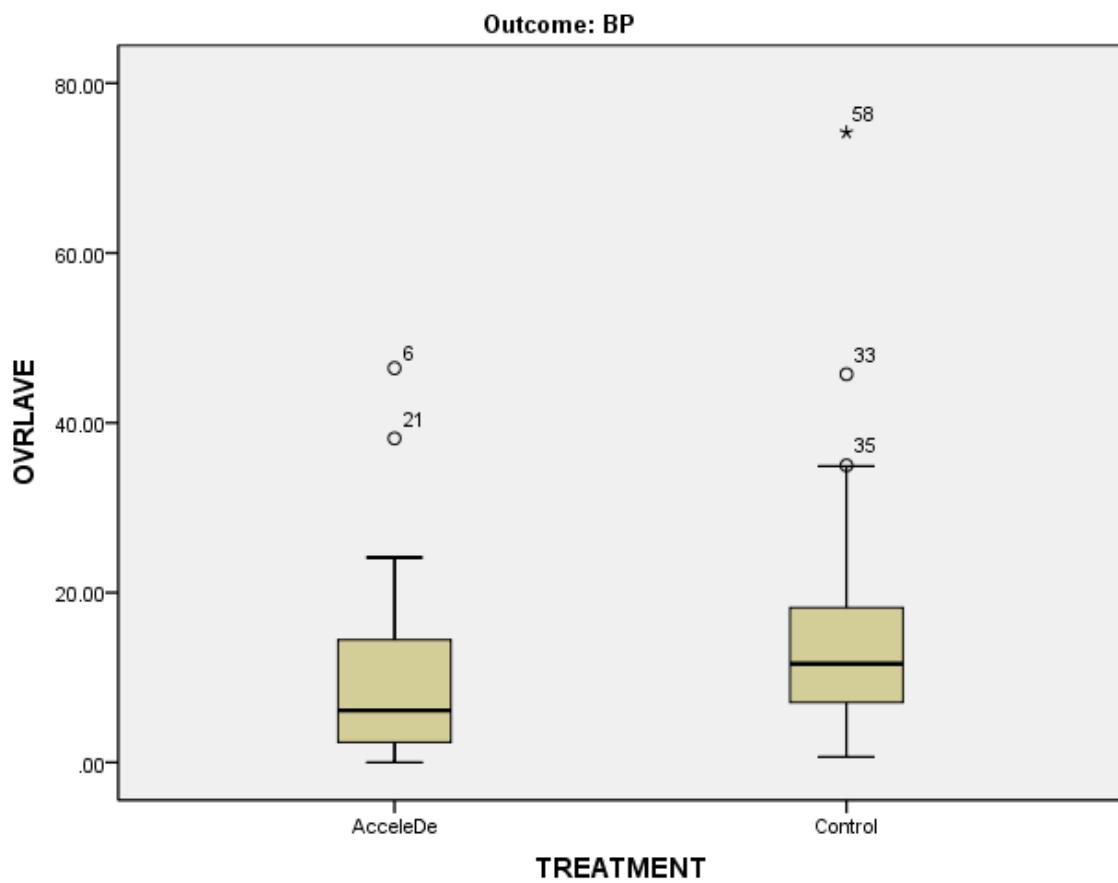
| Month 1 | AcceleDent Overall Pain | AcceleDent Biting Pain | Control Overall Pain | Control Biting Pain |
|----------------|------------------------------------|-----------------------------------|---------------------------------|--------------------------------|
| Day 1 | 18.8 | 25.5 | 31.6 | 40.3 |
| Day 2 | 17.2 | 27.9 | 33.0 | 43.2 |
| Day 3 | 14.2 | 19.7 | 28.5 | 38.4 |
| Day 4 | 9.2 | 13.9 | 23.2 | 33.1 |
| Day 5 | 5.6 | 9.2 | 17.7 | 24.0 |
| Day 6 | 2.4 | 7.0 | 12.1 | 17.2 |
| Day 7 | 1.3 | 2.7 | 8.9 | 11.1 |

Table 4-9. Month 4 Daily Comparisons

| Month 1 | AcceleDent Overall Pain | AcceleDent Biting Pain | Control Overall Pain | Control Biting Pain |
|----------------|------------------------------------|-----------------------------------|---------------------------------|--------------------------------|
| Day 1 | 29.8 | 43.3 | 29.3 | 37.6 |
| Day 2 | 36.8 | 47.8 | 27.8 | 35.6 |
| Day 3 | 24.5 | 35.4 | 24.7 | 31.4 |
| Day 4 | 18.6 | 27.4 | 19.8 | 26.2 |
| Day 5 | 12.9 | 21.5 | 14.1 | 19.6 |
| Day 6 | 11.3 | 16.4 | 11.7 | 17.5 |
| Day 7 | 7.3 | 13.0 | 9.6 | 14.1 |

Box plots were created to illustrate the differences in the interquartile ranges (IQR) for the different pain categories and for each group (Figures 4-1 and 4-2):

Figure 4-1. Box Plots of the Mean Biting Pain



There were multiple outliers for each group, which is to be expected with the subjective assessment of pain.

Figure 4-2. Box Plots of the Mean Overall Pain

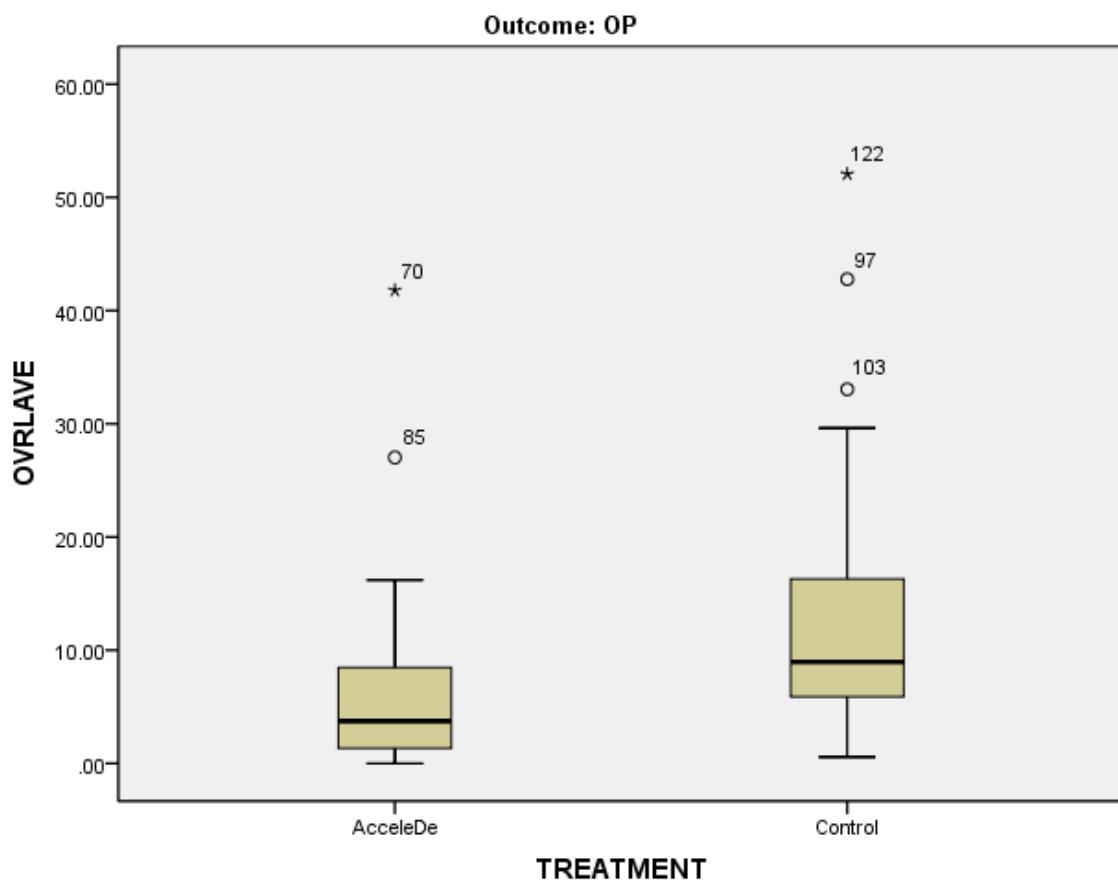


Figure 4-3. Mean Pain Total Study

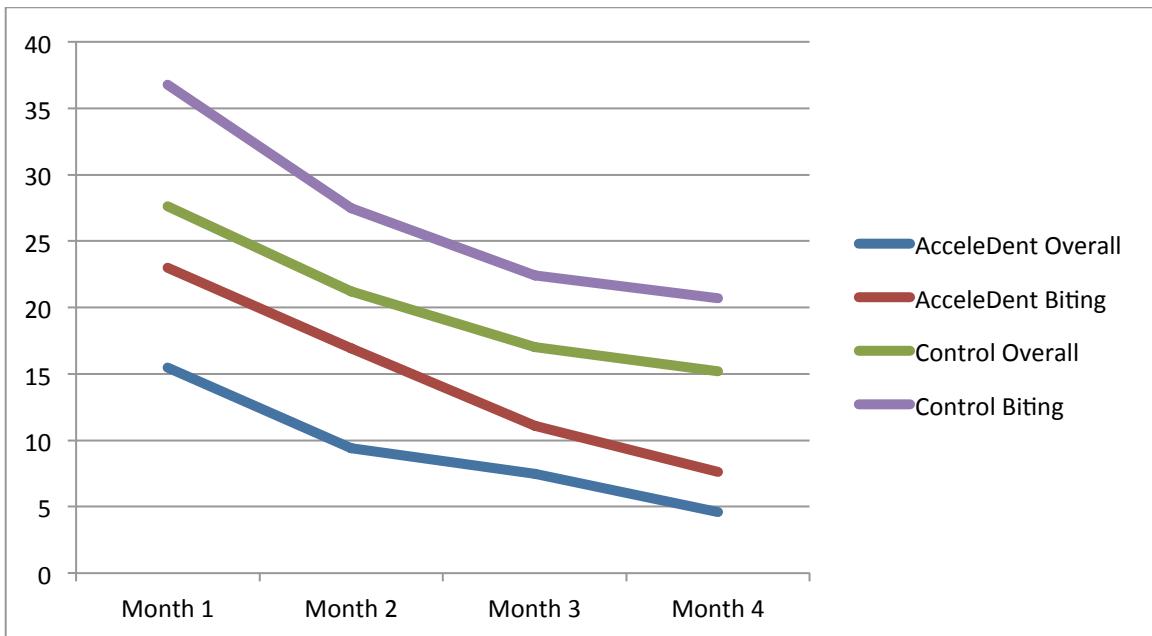


Figure 4-4. Month 1 Mean Weekly Pain

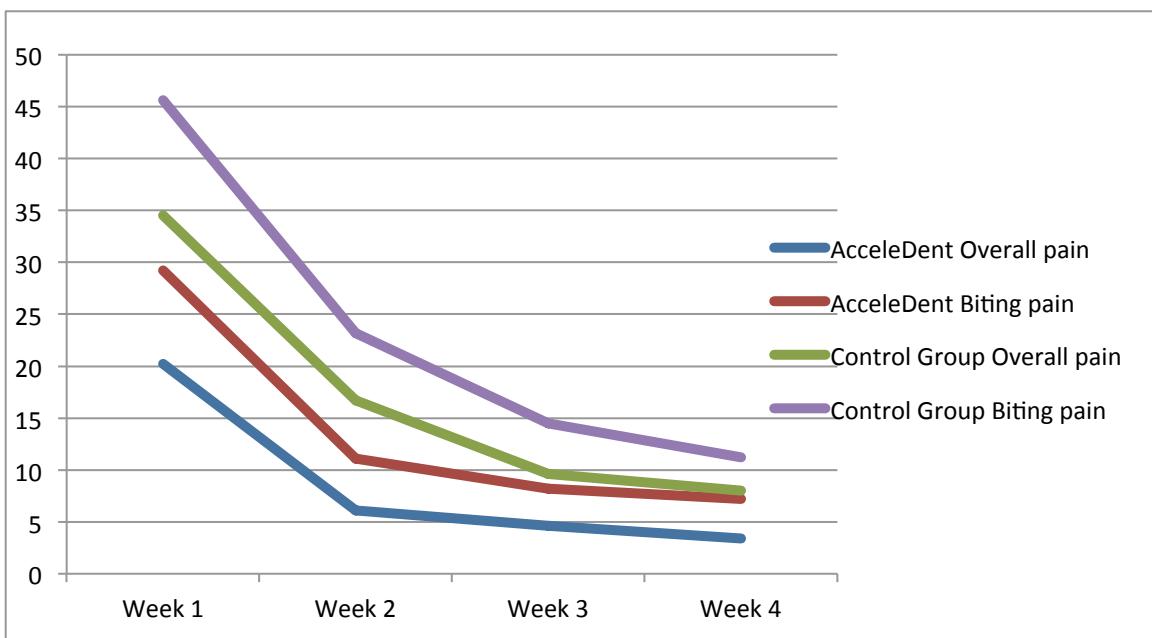


Figure 4-5. Month 2 Mean Weekly Pain

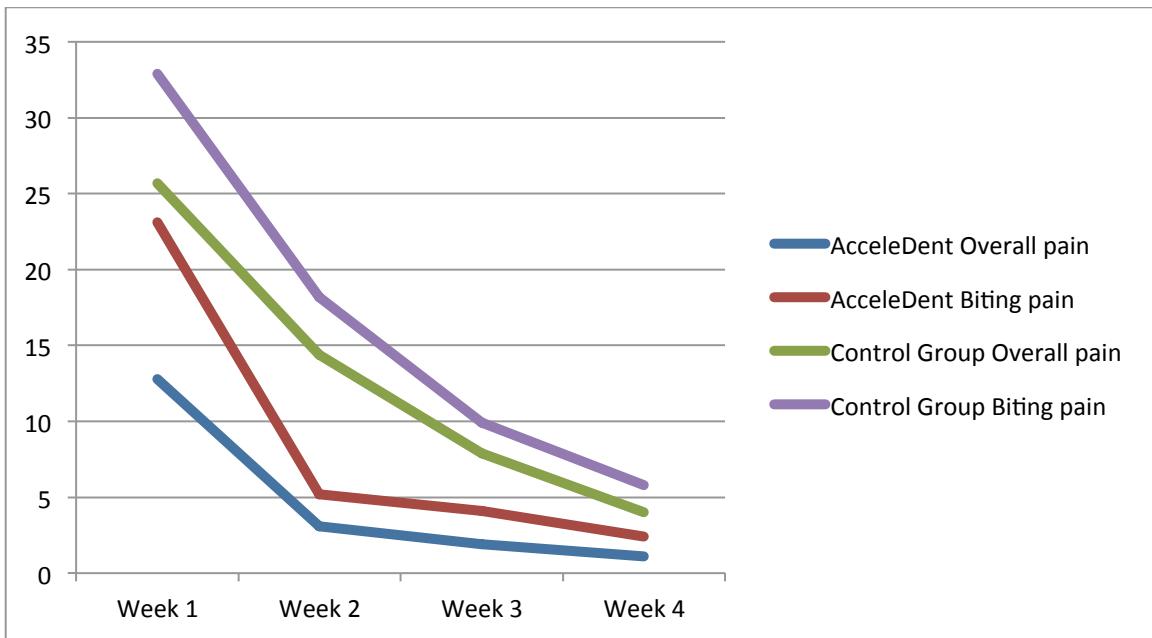


Figure 4-6. Month 3 Mean Weekly Pain

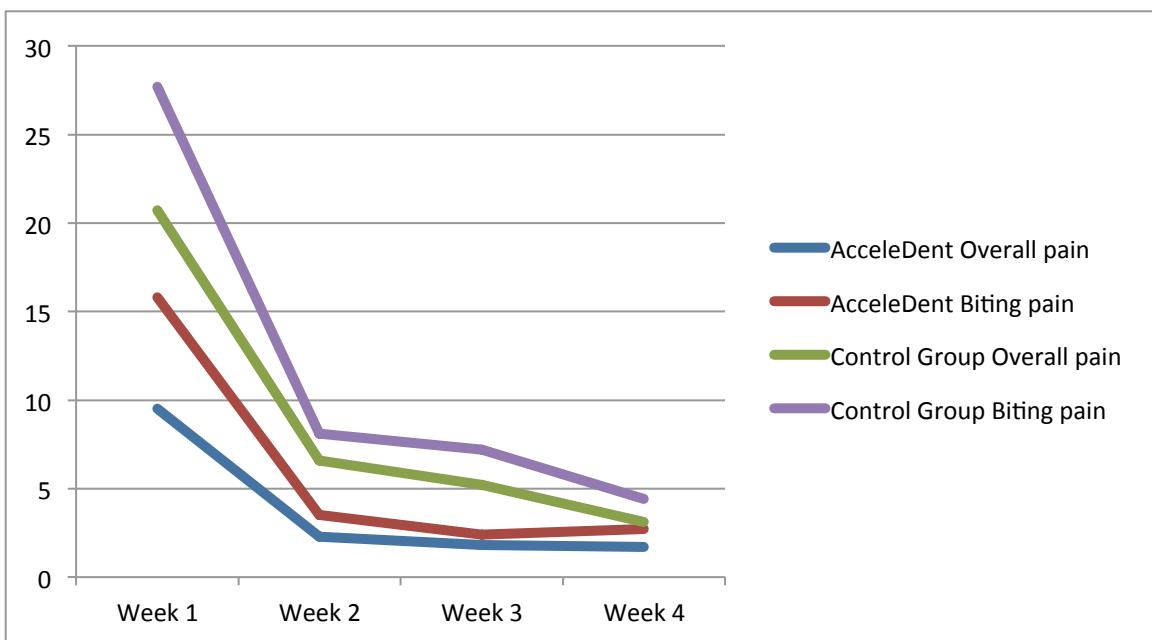


Figure 4-7. Month 4 Mean Weekly Pain

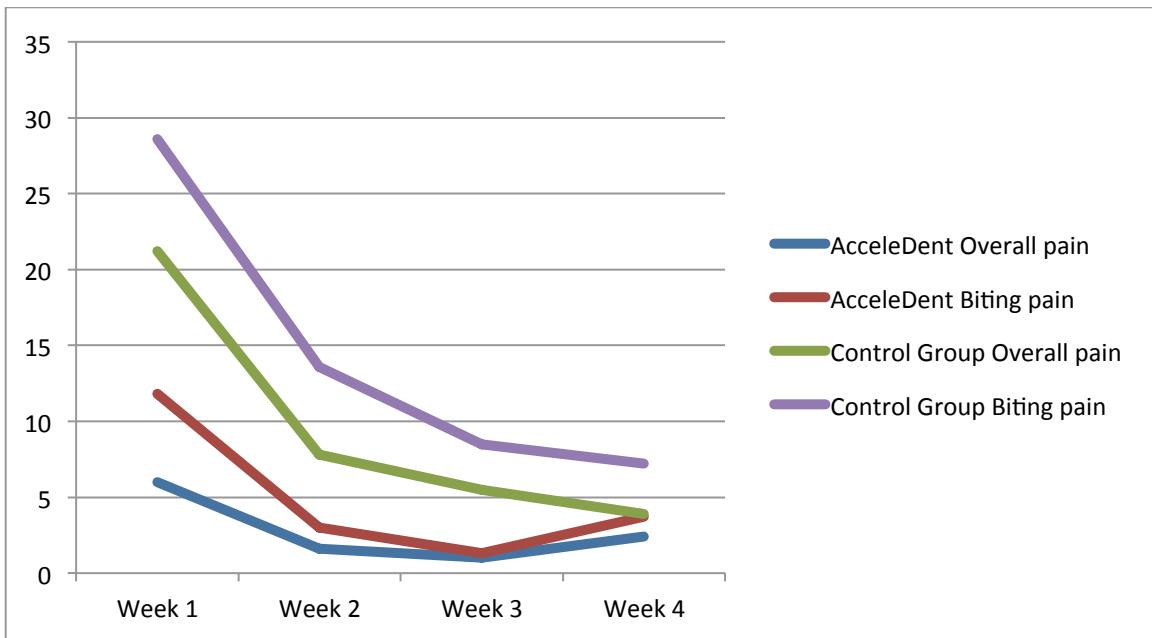


Figure 4-8. Month 1 Mean Daily Pain

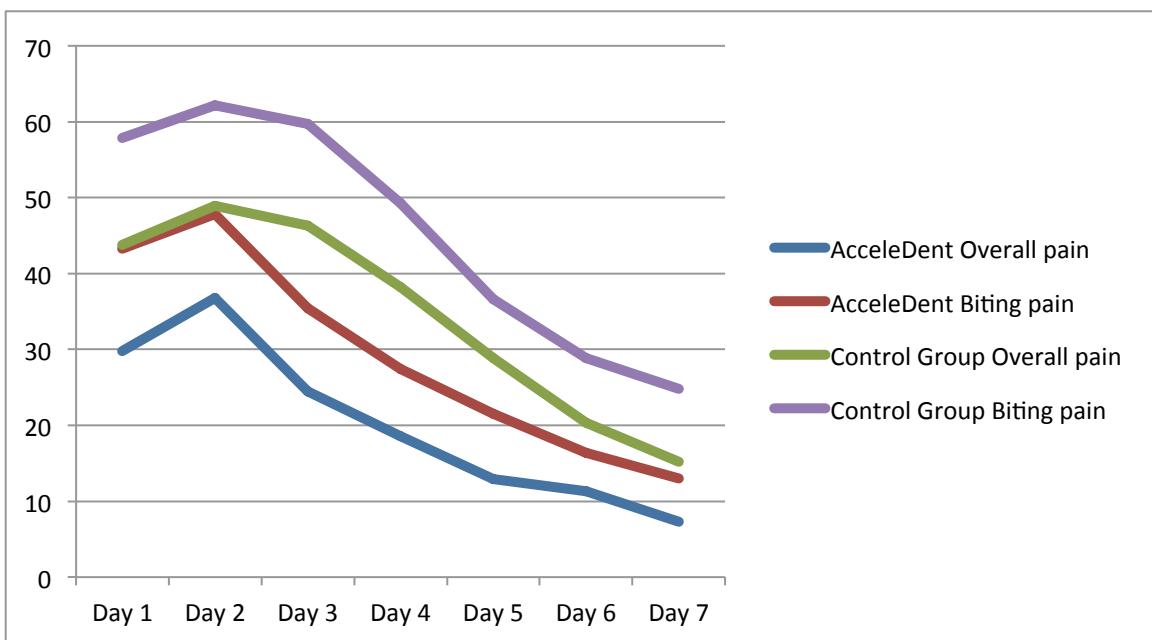


Figure 4-9. Month 2 Mean Daily Pain

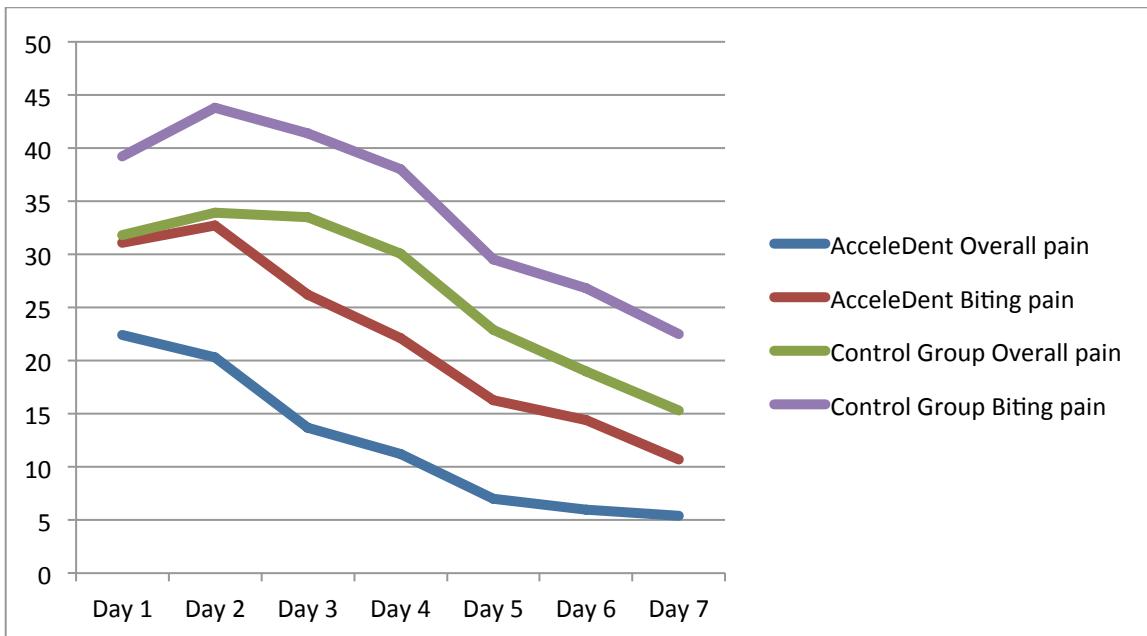


Figure 4-10. Month 3 Mean Daily Pain

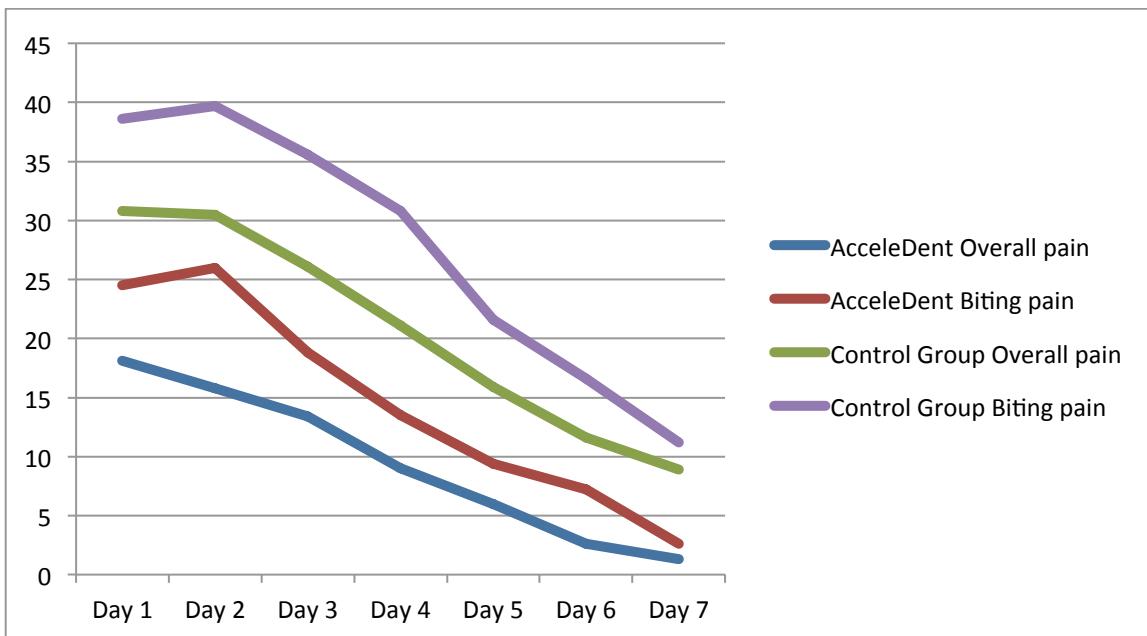
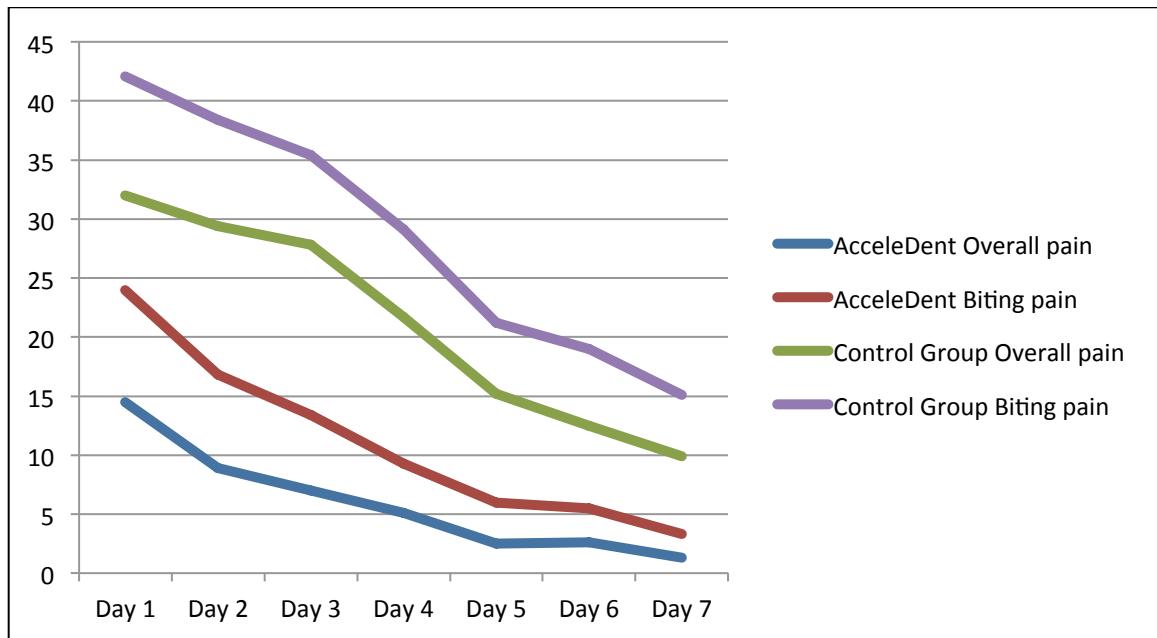


Figure 4-11. Month 4 Mean Daily Pain



V. DISCUSSION

Researchers attribute initial and delayed pain responses following orthodontic treatment to compression and hyperalgesia of the periodontal ligament, respectively (Burstone 1962). According to Polat et al, the periodontal ligament becomes sensitive to released substances such as histamine, bradykinin, prostaglandins, and serotonin. These pain mediators are found in high levels when a pain response occurs. Given that pain is a subjective experience with high variability, it is difficult to assess and few in vivo studies have measured and quantified it. Scheurer et al studied 170 subjects aged 8 to 53 years who completed 8 questionnaires at specific time intervals after insertion of orthodontic appliances. Pain was reported in 65% of the patients after four hours and in 95% of the patients after 24 hours. Pain intensity did not vary by age group, however, patients 13-16 years old reported pain with more frequency and females had a higher perception of pain than males. An unexpected outcome was that while the percentage of patients reporting pain was high, few chose to take analgesic medication. The use of analgesics correlates with the current study, which found self-administered medications were used by 20.7% of the patients in the AcceleDent group and 37.9% of the control group patients.

Multiple studies found that pain after orthodontic procedures peaked around 24 hours post treatment. Ngan et al and Scheurer et al found that pain increased 4 hours post-treatment and gradually returned to baseline levels at 7 days post-treatment; whereas Erdinç and Dinçer found that pain was perceived at 2 hours and then decreased by day 3, with no difference found between either

gender or size of the initial archwire. In this study, pain quickly increased to a peak at around 24 hours after initial archwire or separator insertion, which coincides with previous studies. Both groups showed peak pain around 24 hours post adjustment, however, the AcceleDent group had a significantly decreased pain response on the VAS survey in overall pain. There was also a decreased pain perception between the two groups for biting pain, but it did not show statistical significance. This fits with the current concept that sustained PDL pressure from orthodontic adjustment decreases blood flow and recruitment of the pain producing substances over time. Therefore, increasing blood flow to the PDL by vibratory stimulation at regular intervals would be more effective in obtunding pain. Alternative explanations to be considered are placebo effect and use of medications during the survey period. The placebo effect is a phenomenon in which a fake treatment can sometimes improve a patient's condition simply because the person has the expectation that it will be helpful. A sham device was not utilized in the current study for several reasons: 1) Possible skewed results because the bite plate could essentially function as a bite wafer; 2) the premise of misleading the patient (i.e. "the vibration is so slight you may not feel anything at all"); and 3) difficulty in obtaining sham devices in time for this study.

Adaptation to appliances and willingness to undergo orthodontic treatment may be influenced by attitude, learned behavior, and prior expectation of pain intensity. Sergl et al indicated that predictability for patient acceptance of orthodontic fixed appliances might stem from the initial amount of patient pain and discomfort. In the same paper they reported that patients generally adapt to

pain and discomfort during the first 3 to 5 days after placement of the fixed appliances and that patients with removable appliances reported less pain. Additionally those who viewed their malocclusion as more severe seemed to adapt faster to appliances and document less pain. Bergius et al found that perceived pain following separator placement was highly correlated with low motivation for orthodontic treatment, high dental anxiety, low activity temperament, and a high pain rating from vaccinations. This correlates with an earlier study finding of Bergius et al showing possible differences in pain response based upon culture, gender, age, cognition, and emotion. Several studies demonstrate that females experience greater pain than males during orthodontic treatment while others found no gender-related differences in pain experienced during orthodontic treatment. In the present study females used more over the counter (OTC) medications across all time points. Several studies investigated the effect of different types of archwires on the level of pain experienced. Erdinc and Dincer et al found no difference between 0.014" and 0.016" nickel titanium (NiTi) archwires and Fernandes et al found no difference between superelastic NiTi and conventional NiTi archwires or conventional NiTi and stainless steel archwires.

A VAS was used in the current study for pain assessment. This scaled survey gives the respondent the freedom to choose the exact intensity of the pain and it is a reliable and sensitive method of measuring pain and the effect of pain reducing methods. In most situations, individuals over the age of 5 years are able to understand and complete this task. Many orthodontic pain studies have utilized the VAS survey. Others have included a questionnaire with

agree/disagree and positive/negative statements, sometimes referred to as the verbal rating scale and numerical rating scores from 0 to 10. Both are considered less sensitive than visual analog scales. Since the patients in this study ranged from 10-53 years old, the VAS survey was deemed the most ideal, since it is easy to understand and utilize. Patients were given a detailed explanation and demonstration on filling out the VAS survey properly.

At the time of this study, there is no universal agreement regarding the use of analgesics in orthodontic pain reduction. Various pharmacologic therapies have been suggested to control pain resulting from orthodontic treatment. Non-steroidal anti-inflammatory drugs (NSAIDs) are commonly utilized because they effectively reduce the concentration of prostaglandins. Erdinç and Dinçer reported that among adolescents, analgesic use peaked at 6 hours post archwire insertion regardless of wire size or gender, and then decreased gradually. Ngan et al suggested that 400 mg ibuprofen is the preferred analgesic for post-orthodontic adjustment pain when compared to 650 mg of aspirin or a beta-lactose placebo. Similarly, Bernhardt et al recommended a pre-emptive dose of ibuprofen to reduce pain after separator placement. Polat et al found that patients taking naproxen sodium had greater pain relief after initial archwire placement than those taking either ibuprofen or a placebo. In another study Polat et al compared ibuprofen, flurbiprofen, naproxen sodium, aspirin, and a placebo and concluded that the use of naproxen sodium or aspirin resulted in the lowest levels of reported pain. All four of these studies utilized a VAS scorecard for documentation of pain.

Recently the use of NSAIDs for the reduction of pain caused from orthodontic treatment has been questioned. Non-orthodontic adverse side effects from use of NSAIDS, such as gastric ulceration, bleeding disorders, and allergic reactions, have led researchers and clinicians to seek safer alternatives. In addition to the more commonly known side effects of NSAIDS, animal studies showed possible inhibition of orthodontic tooth movement, while Kyrokanides et al found that inhibition of cyclooxygenase activity altered the potential of endothelial cells to remodel extracellular matrix components. They believed this effect resulted from a reduction in the number of osteoclasts and inhibition of prostaglandin synthesis. Alternatively, Walker and Buring suggested acetaminophen for treating orthodontic pain as an alternative to NSAIDs. A study by Salmassian et al found that acetaminophen, ibuprofen, and a placebo were all equally effective in reducing discomfort following initial archwire placement, when measured on a VAS survey. This suggests that the actual pain level is not as significant as previously suggested and that a placebo or provider reassurance may be as effective as OTC medications. Some of the previously mentioned studies suggest that NSAID therapy may be counterproductive to orthodontic tooth movement and therefore a non-pharmacologic means of pain alleviation should be considered as a viable alternative. In the current study, medication usage was evaluated for both groups. Pain medication usage was reported by 20.7% of the AcceleDent subjects and 37.9% of the control subjects. Of the AcceleDent and control group patients that used pain medication, 10.3% and 24.1% reported taking ibuprofen, respectively. The reasons cited for taking pain medicine in the AcceleDent group were evenly distributed (33.3%) between

extractions, headache and no reason. The reasons cited for taking pain medicine in the Control group were extractions (<1%), headache (18.2%) and no reason (72.7%). This study found similar pain and OTC medication use trends as previous studies, however, the use of vibration therapy appeared to significantly decrease the need for pain medications and increase patient comfort.

Non-pharmacological pain management may have significant patient benefits ranging from increased tooth movement, decreased medication risks, and greater comfort. One non-analgesic pain relief approach utilized a mechanical means to loosen the tightly grouped fibers around the nerves and blood vessels, restoring normal vascular and lymphatic circulation, with the intention of relieving inflammation and edema. An example of this is a plastic bite wafer that the patient chews on periodically after an orthodontic procedure. The bite wafer is typically a U-shaped, moderately hard plastic wafer approximately 2-4mm thick. Murdock et al found that plastic bite wafers chewed by the patient were as effective as OTC pain medications after initial archwire placement. Hwang et al found that pain relief occurred in 56% of patients after using a bite wafer, however, the other 44% of the patients reported increased discomfort. Unlike the previous study, Otasevic et al found that their bite wafer group reported more pain than the group that avoided masticatory activity, which challenges the use of bite wafers for pain reduction.

Another treatment approach, low level laser therapy (LLLT), has also been explored. LLLT is defined as laser treatment in which the energy output is low enough to prevent a rise in the temperature of the treated tissue above normal

body temperature. The mechanism of this is believed to be laser anti-inflammatory and regenerative effects on neurons. Turhani et al found decreased pain with the use of LLLT after placement of fixed appliances and the initial archwire at 6 and 30 hours post-treatment between a test group and a blinded control group who received a placebo laser treatment. Fujiyama et al also found that LLLT significantly reduced pain. Tooth movement was unaffected by the laser therapy when compared to the control group.

The vibratory stimulation used in this study is another non-pharmacologic and non- invasive method of pain control. Lundeberg et al, in a study unrelated to orthodontics, found a reduction in chronic musculoskeletal pain with the use of vibration. The greatest pain relief on a VAS survey was in the range of 25-40 minutes with vibration therapy. An overall reduction of pain occurred in 69% of patients. Roy et al studied vibratory stimulation therapy on temporomandibular joint disorders (TMD) using VAS surveys. The extent and severity of TMD pain were both reduced with 100 Hz of vibrotactile stimulation. Along with TMD pain, high frequency vibrotactile stimulation of teeth has proven effective in alleviating pain. Ottoson et al described the effect of vibratory stimulation on pain of dental origin in 36 patients with varied types of dental pain. An effective reduction of the intensity of the pain was experienced by 83% of patients, with the majority experiencing greater than 50% reduction of pain. In a similar study, the stimulus frequency was altered, using vibration at 100 Hz and 240 Hz. The results suggested that the dental pain threshold was elevated shortly after use, up to 1 minute or less, but that both frequencies were equally effective (Kempainen, 1983). Nishimura et al found similar results in animal studies. They confirmed

an increased rate of tooth movement, and showed activation of a chemical messenger pathway, RANKL, which is a crucial factor for osteoclast formation and function.

Ste. Marie et al explored the effect of resonance vibration on tooth pain. They reported a substantial decrease of pain in orthodontic patients post adjustment following the use of a vibratory device. The study concluded that use of a vibratory device before the initial onset of pain significantly reduced the discomfort. However, if the vibratory device was used after the onset of pain it was poorly tolerated. The current study initiated vibration therapy in office immediately after separator or archwire placement to ensure patients were comfortable using the device and also to standardize treatment. The significant decrease in pain indicated that vibration therapy significantly improved patient perception of pain. Actual device use by the patient is a confounding variable in the study, with compliance ranging from 36-100% and an average use of 70%. This could also explain the variable results obtained from bite wafer studies. Vibration therapy in this study resulted in significantly lower perceived pain and less OTC medication use. Therefore, it may be a safer, more effective means of post-orthodontic adjustment pain control.

VI. CONCLUSIONS

1. Perceived post-orthodontic adjustment pain reaches a peak at approximately 24 hours and then gradually subsides.
2. Pain is subjective and highly variable.
3. Use of the AcceleDent Aura device had a significant effect on pain reduction over time.
4. Pain levels decreased in both the AcceleDent and control groups over time regardless of treatment modality.

VIII. LITERATURE CITED

- Arias OR, Marquez-Orozco MC. Aspirin, acetaminophen, and ibuprofen: their effects on orthodontic tooth movement. *Am J Orthod Dentofacial Orthop* 2006;130:364-70.
- Bartlett BW, Firestone AR, Vig KW, Beck FM, Marucha PT. The influence of a structured telephone call on orthodontic pain and anxiety. *Am J Orthod Dentofacial Orthop* 2005;128:435-41.
- Bergius M, Kiliaridis S, Berggren U. Pain in orthodontics. A review and discussion of the literature. *J Orofac Orthop* 2000;61:125-37.
- Bergius M, Broberg A, Hakeberg M. Prediction of prolonged pain experiences during orthodontic treatment. *American Journal of Orthodontics & Dentofacial Orthopedics* 2008;133:339.e1-339.e8.
- Bergius M, Berggren U, Kiliaridis S. Experience of pain during an orthodontic procedure. *Eur J Oral Sci*. 2002;110:92–98.
- Bernhardt MK, Southard KA, Batterson KD, Logan HL, Baker KA, Jakobsen JR. The effect of preemptive and/or postoperative ibuprofen therapy for orthodontic pain. *Am J Orthod Dentofacial Orthop* 2001;120:20-7.
- Brown DF, Moerenhout RG. The pain experience and psychological adjustment to orthodontic treatment of preadolescents, adolescents, and adults. *Am J Orthod Dentofacial Orthop* 1991;100:349-56.
- Doll GM, Zentner A, Klages U, Sergl HG. Relationship between patient discomfort, appliance acceptance and compliance in orthodontic therapy. *J Orofac Orthop* 2000;61:398-413.
- Erdinç AM, Dinçer B. Perception of pain during orthodontic treatment with fixed appliances. *Eur J Orthod* 2004;26:79-85.
- Fernandes LM, Ogaard B, Skoglund L. Pain and discomfort experienced after placement of a conventional or a superelastic NiTi aligning archwire. A randomized clinical trial. *J Orofac Orthop* 1998;59:331-9.
- Firestone AR, Scheurer PA, Burgin WB. Patients' anticipation of pain and pain-related side effects, and their perception of pain as a result of orthodontic treatment with fixed appliances. *Eur J Orthod* 1999;21:387-96.
- Fujiyama K, Deguchi T, Murakami T, Fujii A, Kushima K, Takano-Yamamoto T. Clinical effect of CO₂ laser in reducing pain in orthodontics. *Angle Orthod* 2008;78:299-303.

Furstman L, Bernick S. Clinical Considerations of the periodontium. Am J Orthod 1972;61:138-55.

Hwang JY, Tee CH, Huang AT, Taft L. Effectiveness of thera-bite wafers in reducing pain. J Clin Orthod 1994;28(5):291-2.

Jones ML, Chan C. Pain in the early stages of orthodontic treatment. J Clin Orthod 1992;26:311-3.

Kempainen, P. Modification of human dental-pain thresholds by conditioning vibratactile stimulation at high frequency. Archives of Oral Biology 1983;28:959–962.

Krishnan V. Orthodontic Pain: From Causes to management—A Review. Eur J Orthod. 2007;29:170-9.

Lundeberg T, Nordemar R, Ottoson D. Pain alleviation by vibratory stimulation. Pain 1984;20:25-44.

Marie SS, Powers M, Sheridan JJ. Vibratory stimulation as a method of reducing pain after orthodontic appliance adjustment. J Clin Orthod 2003;37:205-8.

Murdock S, Phillips C, Khondker Z, Hershey HG. Treatment of pain after initial archwire placement: a noninferiority randomized clinical trial comparing over-the-counter analgesics and bite-wafer use. Am J Orthod Dentofacial Orthop 2010;137:316-23.

Ngan P, Wilson S, Shanfeld J, Amini H. The effect of ibuprofen on the level of discomfort in patients undergoing orthodontic treatment. Am J Orthod Dentofacial Orthop 1994;106:88-95.

Ngan P, Kess B, Wilson S. Perception of discomfort by patients undergoing orthodontic treatment. Am J Orthod Dentofacial Orthop 1989;96:47-53.

Nishimura M, Chiba M, Ohashi T, Sato M, Shimizu Y, Igarashi K, Mitani H. Periodontal tissue activation by vibration: intermittent stimulation by resonance vibration accelerates experimental tooth movement in rats. Am J Orthod Dentofacial Orthop 2008;133:572-83.

Oliver RG, Knapman YM. Attitudes to orthodontic treatment. Br J Orthod 1985;12:179- 88.

Otasevic M, Naini FB, Gill DS, Lee RT. Prospective randomized clinical trial comparing the effects of a masticatory bite wafer and avoidance of hard food on pain associated with initial orthodontic tooth movement. Am J Orthod Dentofacial Orthop 2006;130:6.e9-15.

- Ottoson D, Ekblom A, Hansson P. Vibratory stimulation for the relief of pain of dental origin. *Pain* 1981;10:37-45.
- Polat O, Karaman AI, Durmus E. Effects of preoperative ibuprofen and naproxen sodium on orthodontic pain. *Angle Orthod* 2005;75:791-6.
- Polat O, Karaman AI. Pain control during fixed orthodontic appliance therapy. *Angle Orthod* 2005;75:214-9.
- Roy EA, Hollins M, Maixner W. Reduction of TMD pain by high-frequency vibration: a spatial and temporal analysis. *Pain*. 2003;101:267–74. doi: 10.1016/S0304- 3959(02)00332-9.
- Salmassian R, Oesterle LJ, Shellhart WC, Newman SM. Comparison of the efficacy of ibuprofen and acetaminophen in controlling pain after orthodontic tooth movement. *Am J Orthod Dentofacial Orthop* 2009;135:516-21.
- Scheurer PA, Firestone AR, Bürgin WB. Perception of pain as a result of orthodontic treatment with fixed appliances. *Eur J Orthod* 1996;18:349-57.
- Sergl HG, Klages U, Zentner A. Pain and discomfort during orthodontic treatment: causative factors and effects on compliance. *Am J Orthod Dentofacial Orthop* 1998;114:684-91.
- Seymour RA. The Use of Pain Scales in Assessing the efficacy of analgesics in post- operative dental Pain. *Eur J Clin Pharmacol* 1982;23:441-4.
- Shanfield J, Jones J, Laster L, Davidovitch Z. Biomechanical Aspects of Orthodontic Tooth Movement. I. Cyclic Nucleotide and Prostaglandin Concentrations in tissues surrounding orthodontically treated teeth in vivo. *Am J Orthod Dentofacial Orthop* 1986;90:139-48.
- Turhani D, Scheriau M, Kapral D, Benesch T, Jonke E, Bantleon HP. Pain relief by single low-level laser irradiation in orthodontic patients undergoing fixed appliance therapy. *Am J Orthod Dentofacial Orthop* 2006;130:371-7.